II. SUMMARY AND CERTIFICATION

K092158

A. 510(k) Summary

JAN 14 2010

Submitter: SterilMed, Inc.

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Date Prepared: July 14, 2009

Trade Name: Reprocessed Electrophysiology Diagnostic Catheters

Classification Name: Electrode Recording Catheter or Electrode Recording Probe

Classification Number: Class II, 21 CFR 870.1220

Product Code: NLH

Predicate Devices:	The reprocessed EP diagnostic catheters are substantially equivalent to St. Jude Medical Reflexion™ catheters.
Device Description:	SterilMed Reprocessed Reflexion EP diagnostic catheters consist of a shaft with a handle at the proximal end, and are considered to be steerable. These catheters have an outer diameter of either 6 or 7F and are either 99 or 105cm in length, with 2 – 20 platinum, radiopaque tip electrodes and a variety of inter-electrode spacing's and curve styles at the distal tip. The distal tip is steerable and cables connect to the handle and interface between the catheter and an external stimulator and /or an electrophysiological recorder. Note: Only the catheter is the subject of this submission, the external stimulator and /or electrophysiological recorder and any other related equipment are not included in the scope of this submission.
Intended Use:	The reprocessed EP diagnostic catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, cardiac stimulation, and for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.
Functional and Safety Testing:	Representative samples of reprocessed EP diagnostic catheters were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Conclusion:	The reprocessed EP diagnostic catheters are substantially equivalent to the St. Jude Medical Reflexion™ electrophysiology diagnostic catheters. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

SterilMed, Inc
c/o Mr. Garrett Ahlborg
Regulatory Affairs Manager,
1400 73rd Avenue North, Suite 100
Maple Grove, MN 55369

JAN 14 2010

Re: K092158
Reprocessed Electrophysiology Catheters (See Enclosed List)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: NLH
Dated: December 22, 2009
Received: December 23, 2009

Dear Mr. Ahlborg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092158

Device Name: Reprocessed Electrophysiology Diagnostic Catheters

Indications for Use:

The reprocessed electrophysiology diagnostic catheters are indicated for temporary use during electrophysiology studies for intracardiac sensing, recording, cardiac stimulation, and for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna D. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092158